Approaches to ventricular assist device exchange: Resternotomy versus limited incisions

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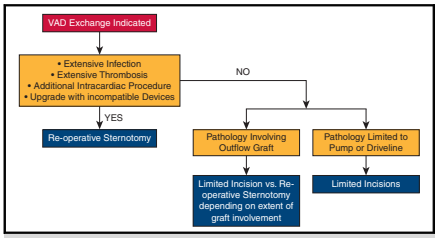

Suggested algorithm for choice of surgical approach to VAD exchange.

CENTRAL MESSAGE

The surgical approach to LVAD exchange is determined by several factors, including the indication for exchange, extent of pathology, planned additional intracardiac procedures and surgeon expertise.

See Commentaries on pages 100 and 102.

The prevalence of end-stage heart failure (HF) is on the rise in the United States, matching concurrent increases in the age of the population and the rates of comorbid conditions such as obesity.[1] Although heart transplantation remains the preferred treatment option for patients with end-stage heart failure, donor hearts remain a limited resource with demand that significantly outweighs supply. Left ventricular assist devices (LVADs) provide a viable option for patients with HF, with each new device generation offering improved survival and decreased occurrence of complications.[2] Notwithstanding, LVAD complications still occur at nontrivial rates, with ventricular assist device (VAD) exchange being a necessity in severe cases. In this article, we describe the procedural options for LVAD exchange, contrasting surgical approaches and outcomes associated with each of these methods. This in-depth discussion of options for exchange is timely given the recent Food and Drug Administration class 1 recall of one of the mostly commonly used LVADs.[3] Ultimately, we avoid a general recommendation for one specific surgical approach to LVAD Exchange, advocating instead for a strategy of thoughtful selection from available techniques, factoring in specific patient factors and unique consideration of the pathology that necessitates LVAD exchange.

CONTEMPORARY VENTRICULAR ASSIST DEVICES AND KEY FEATURES

Over the past several years, the most commonly implanted intracorporeal LVADs include the HeartMate II (Abbott Cardiovascular) axial LVAD (HM-II), the HeartWare (Medtronic) centrifugal LVAD (HVAD), and the HeartMate III (Abbott Cardiovascular) centrifugal LVAD (HM-III). Currently, the HM-III is the only Food and Drug Administration–approved centrifugal pump on the market following class 1 recalls of the HVAD in the summer of 2021. Recalls were initiated among the concerns about pump failure and higher rates of neurologic events.[3]

While a detailed consideration of the development of these devices is beyond the scope of this article, it is important to note specific design features that should be considered when planning a device exchange. A significant improvement in clinical outcomes over first-generation devices was noted with engineering that limited the number of moving mechanical parts in LVADs.[4] The HM-II is an axial flow device that was the main "second-generation" LVAD, whereas the HVAD and HM-III are magnetically levitated centrifugal flow devices that make up the "third generation" of LVAD technology. At the time of initial implantation, second- and third-generation devices require access to the left ventricular apex and the proximal ascending aorta for attachment of the inflow and outflow components. This can be achieved via full sternotomy or a range of "limited-incision" approaches to individually access the LV apex (left thoracotomy vs subcostal vs subxiphoid) and the aorta (upper partial-sternotomy, right anterior thoracotomy).[5] The approach to initial LVAD placement is in part determined by the characteristics of the patient and his/her mediastinum and subsequently affects options for

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approach should device exchange become necessary. Although all contemporary devices have modular designs that allow for exchange of specific parts based on the etiology of failure, these components are generally incompatible across different device types. For this reason, LVAD exchanges involving device upgrades often require maximal exposure with resternotomy for replacement of all device components. Notwithstanding, reports of device upgrade retaining components of the initial LVAD have been published.[6,7]

INDICATIONS FOR VENTRICULAR ASSIST DEVICE EXCHANGE

There are several indications for VAD exchange, including device malfunction, pump thrombosis, device malpositioning (improper inflow positioning or outflow graft kinking), and infection.[1,6,8] Diagnosis is made using a combination of clinical signs, laboratory data, and imaging studies, often including computed tomography (CT) scan. The frequency of these complications varies across studies and device types, but there is consistency in descriptions of the superiority of VAD exchange over medical management.[9,10] Rates of recurrence of thrombosis and infection are approximately 2-fold when medical management is attempted instead of VAD exchange, acknowledging that many of these studies are not robustly powered. With newer-generation centrifugal devices, there has been some success managing pump thrombosis with systemic or localized thrombolytic therapy, although with considerable rates of rethrombosis.[11,12] In all cases, careful consideration must be given to the risk of hemorrhage with thrombolytics weighed against the risks of device exchange. VAD exchange generally remains an option in the setting of lysis failure.

Intuitively, it follows that limited incisions should be associated with less morbidity because they require less dissection of the reoperative mediastinum. However, the reality of approach selection for VAD exchange is more nuanced with the indication for surgery playing a critical role in determining the options.[13,14] Other considerations include individual patient anatomy and plans for additional intracardiac operations. In the simplest scenario, pump thrombosis, pump malfunction, and isolated driveline failure, without involvement of the outflow graft, can be managed by simply exchanging the pump itself. The modular design of modern LVADs makes this achievable because a new pump can be attached to the other components of the LVAD. The limited incision approach is ideal here. Other scenarios are less straightforward. In the case of thrombosis involving the outflow graft, it is generally best to exchange the entire outflow graft, which requires resternotomy for dissection of the aortic anastomosis. In some scenarios with limited graft involvement, the nonthrombosed portion of the graft without thrombosis may be left in situ and grafted end-to-end with the new device. In the case of device infection, clinical assessment may guide decisions about which LVAD components to replace, but the safest option will generally involve replacement of all hardware to ensure adequate source control. Additionally, typical tenets of infection control must be respected, including robust irrigation and debridement of infected tissues, and consideration for re-siting of LVAD components. It is reasonable in these cases to pursue resternotomy to maximize the likelihood of complete eradication of infection.

In choosing between treatment options for patients with LVAD pathology, some consideration must be given to the option of high priority listing and urgent transplantation. Patients with LVAD-associated difficulties (including angioectasia and other bleeding complications) and other advanced intracardiac pathology make a case for this strategy. In all cases, clinical status, risk of reoperation, and candidacy for transplantation must be considered in nuanced multidisciplinary deliberations. In patients with LVADs who have demonstrated enough recovery of cardiac function, the option of pump removal with plugging of the sewing ring may be explored. Finally, in patients with poor operative and transplant candidacy (including anatomic, functional, and social factors), and ineligibility for medical therapy, difficult conversations about goals of care (including palliative care specialists) should be initiated early to achieve outcomes that are consistent with patients' preferences.

SURGICAL TECHNIQUE AND CONSIDERATIONS

Resternotomy

The technique for resternotomy for LVAD exchange is similar to that used for other reoperative cardiac surgery with an emphasis placed on careful dissection around pump components. Careful study of axial imaging (typically contrast-enhanced CT scan) is paramount and will help the surgeon anticipate perilous portions of the dissection. Imaging may inform decision-making about the approach to exchange if critical anatomy is at risk of injury or may be difficult to access from either approach. In patients in whom safe reentry is anticipated, cardiopulmonary bypass (CPB) can be established centrally after the aorta and right atrium are exposed. In the patient with a hostile mediastinum, peripheral CPB may be necessary. With or without CPB, LVAD flows should be kept at the lowest possible rate required to sustain systemic perfusion because inadvertent outflow graft injury may be followed by catastrophic air embolism within as few as 2 cycles of a fully flowing pump.[4] In addition to mitigating the risks of significant air embolism by permitting lower flow rates, CPB allows for cardiac decompression, which facilitates dissection. The maximal operative field achieved with resternotomy permits removal and replacement of all existing

LVAD components This is especially important in the setting of extensive infection and for exchanges involving older LVADs when surgeons may take the opportunity to upgrade devices.[15,16]

Once the left ventricular apex and outflow graft have been exposed, the outflow graft is clamped and divided, and the pump is explanted. In exchanges performed for etiologies other than infection, the sewing ring can usually be left in situ. With some ingenuity, the sewing ring may even be left in situ for VAD exchanges that involve model changes.[6,17] However, infection involving the sewing ring or irremediable device incompatibility will necessitate replacement. If the original ring was appropriately located, the dissection should proceed carefully, anticipating placement of the new ring in the same location at the left ventricular apex. In the rare situation that a new location must be picked for ring siting (ie, in the setting of extensive tissue destruction or improper location of the initial ring), a site should be selected that will offer unobstructed blood flow into the inflow cannula. The original ring location may be closed using felt-reinforced Prolene mattress sutures. After the new pump has been secured, the outflow graft is replaced (generally using a side-biting aortic clamp). Standard deairing maneuvers are performed, and the new pump is carefully restarted.

For both sternotomy and limited approaches, there may be an opportunity to mitigate the risk of embolism using cerebral embolic protection devices. Although there are no reports of application of this technology in LVAD exchange, there are reports of success in other high-risk open-chamber cardiac surgery.[18]

Subcostal, Thoracotomy, and Subxiphoid Approaches

As noted earlier, the less bulky, modular design of newer-generation LVADs has facilitated the development of techniques for exchange that require limited chest incisions (Figure 1). Generally, these approaches are most applicable when pathology is limited to the pump or drive line. A careful study of imaging is critical to guide decision making. The choice among limited incisions is driven by surgeon experience, patient habitus, and specific details of the case. These approaches usually require some degree of right lateral decubitus positioning with lung isolation via a double lumen endotracheal tube. With left thoracotomy, partial rib resection is required in as much as 50% of cases for adequate visualization and access.[17] The subcostal approach may be used without rib resection; however, careful attention must be paid to tension-free reapproximation of muscle and fascia to avoid wound dehiscence.[19] For this approach, any of several internal thoracic artery retractors may be used for chest wall elevation.

Often, the femoral vessels are cannulated for CPB, although some centers have successfully exchanged LVADs off-pump, usually in stable patients requiring exchanges of limited components.[20] In all cases, but especially when exchange is performed off-pump, thoughtful strategies for outflow graft clamping and deairing are necessary to avoid air embolism. Adjuncts such as steep Trendelenburg positioning, positive pressure ventilation during the case, and use of interarterial catheters may be used for further deairing. Once the left thoracic cavity has been safely accessed, the LV apex and LVAD pump are exposed. The pump is then exchanged, using the existing sewing ring and outflow graft (usually with a graft-graft anastomosis). In both subcostal and thoracotomy approaches, a separate subxiphoid or right thoracotomy incision is sometimes required for outflow graft access.[21] One center has published reports of a sternal-sparing, muscle-sparing subxiphoid-only approach, noting decreased pain burden for patients.[22]

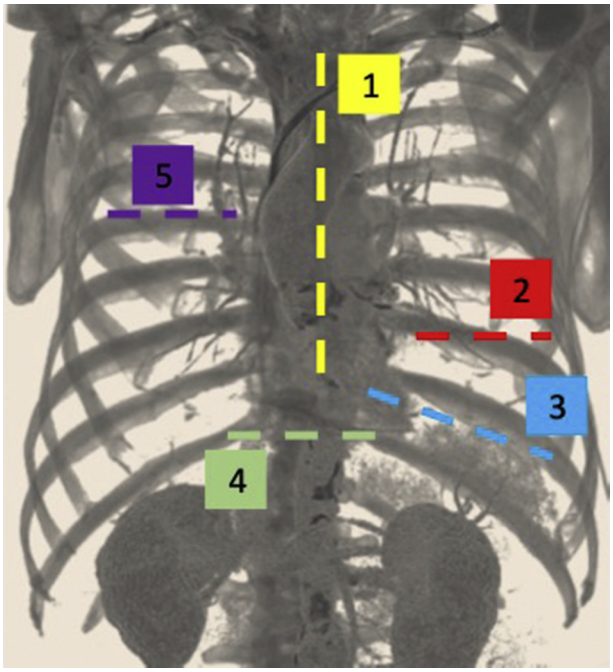

FIGURE 1. Options for approaches to VAD exchange.

Considerations for Specific Combinations of Device Exchange

Despite general incompatibility across device types, reports have been published of successful LVAD upgrade, retaining components of the initial device.[6,7,20] The exchange of an HVAD for a HM-III is likely to be of most interest to practitioners with reports of placement of a HM-III pump within a HVAD ring via thoracotomy.[6,7] The screw tightening feature of the HVAD sewing ring allows for size adjustment to secure the HM-III pump. Leakage around these components is prevented by reinforcing the HM-III inflow using a rubber seal (made out of a rubber glove).

The outflow graft size mismatch (HVAD–10 mm, HM-III–14 mm) is managed by careful end-to-end anastomoses between grafts.

In the case of the HM-II to HM-III exchange, reports have been published leaving the HM-II ring in site with placement of the HM-III pump within the silicon tube of the HM-III ring.[7] The inflow cannula is secured using sterile cable ties tightened around the silicon tube.

COMPARATIVE OUTCOMES WITH RESTERNOTOMY AND LIMITED INCISIONS

Although the data comparing resternotomy with limited incisions for VAD exchange are far from robust and scarcely include patients with the newest devices, analyses consistently demonstrate meaningful short-term advantages for those patients who are candidates for limited incisions (Table 1). In a 2019 study pooling data on VAD exchanges from 4 centers, patients undergoing thoracotomy had lower blood transfusion requirements and shorter intensive care unit stays.[23] Other studies demonstrate additional benefits of limited incisions including shorter operative times and lower occurrence of postoperative complications such as reoperation, prolonged intubation, and acute kidney injury[14,19,22,23-26] (Table 2). One study[19] suggests that patients undergoing VAD exchange via limited incisions are more likely to progress to transplantation, although authors recognize the selection bias that may be reflected.

Some studies suggest high rates of recurrent infection and device thrombosis with limited approaches to LVAD exchange, likely related to retention of affected device components (particularly for HM-II where angulation of the in-flow tubing could lead to recurrent thrombosis) and higher likelihood of missed thrombus in the ventricle or outflow graft.[21] The issue of right ventricular (RV) function after LVAD exchange deserves special mention because RV failure after exchange confers worse outcomes. In addition

TABLE 1. Summary of literature on comparative outcomes of sternotomy versus limited incisions for left ventricular assist device exchange

Authors	Publication year	Approach (N)	Devices exchanged	Significant outcomes (all $P < .05$)
Imamura and colleagues[26]	2020	Sternotomy (N = 2) Subcostal (N = 13)	HM II > HM II (N = 13) HM II > HVAD (N = 1) HVAD > HVAD (N = 1)	- No major clinical differences
Agarwal and colleagues[23]	2019	Sternotomy (N = 19) Left thoracotomy (N = 5)	HM II > HVAD	- Sternotomy with higher transfusion rates (4 units vs 1 unit) - Sternotomy with longer ICU length of stay (8 d vs 6 d)
Kitahara and colleagues[14]	2019	Sternotomy (N = 12) Subcostal (N = 13)	HM II > HM II	- Sternotomy with higher RBC transfusion rates (4.7 units vs 0.3 units) - Sternotomy with longer OR times (534.2 min vs 200.5 min) - Sternotomy with longer CPB times (151.5 min vs 33.1 min) - Sternotomy with higher rates of tracheostomy (41.7% vs 0%) - Sternotomy with higher rates of AKI and HD (33.3% vs 0%)
Tchantchaleishvili and colleagues[22]	2017	Sternotomy (N = 6) Subxiphoid (N = 24)	HM II > HM II	- Sternotomy with longer ICU length of stay (37 d vs 7 d) - Sternotomy with longer hospital length of stay (107 d vs 29 d)
Shaikh and colleagues[25]	2017	Sternotomy (N = 9) Subcostal (N = 7)	HM II > HM II	- No major clinical differences
Levin and colleagues[19]	2015	Sternotomy (N = 12) Subcostal (N = 16)	HM II > HM II	- Sternotomy with lower 1-y survival (63% vs 100%) - Sternotomy with longer CPB times (108.5 min vs 39.0 min) - Sternotomy higher rates of prolonged intubation (41.7% vs 6.25%) - Sternotomy with ICU length of stay (8.6 d vs 4.4 d)
Soleimani and colleagues[24]	2015	Sternotomy (N = 9) Subcostal (N = 8)	HM II > HM II	- Sternotomy with lower survival (33.0% vs 75.0%) - Sternotomy with higher RBC transfusion rates (7.1 units vs 3.5 units) - Sternotomy with longer OR times (222 min vs 131 min) - Sternotomy with longer ICU (13.8 d vs 5.0 d) - Sternotomy with longer hospital length of stay (27.2 d vs 16.4 d) -Sternotomy with higher reoperation rates (44.4% vs 0%)

HM II, HeartMate II Left Ventricular Assist Device; *HVAD*, HeartWare Left Ventricular Assist Device; *RBC*, red blood cell; *OR*, operating room; *CPB*, cardiopulmonary bypass; *AKI*, Acute kidney injury; *HD*, hemodialysis; *ICU*, intensive care unit.

TABLE 2. Options and indications for approaches to ventricular assist device exchange

No. (Reference Figure 1)	Incision	Clinical scenarios
1	Reoperative Sternotomy	- Thrombosis (especially involving outflow graft) - Extensive infection (pump, outflow graft) - Device model change (including upgrade) - Additional intracardiac procedure
2 3 4	Left Thoracotomy Subcostal Subxiphoid	- Thrombosis limited to the pump - Thrombosis involving outflow graft (if combined with No. 5) - Infection limited to drive line - Device model change (including upgrade if options exist for safely matching components from different devices)
5	Right Anterior Thoracotomy	- Adjunct to numbers 2, 3, and 4 (or pathology involving mid-distal outflow graft)

to perioperative optimization of volume status, pulmonary vascular resistance, and entropy, there is some postulation that avoiding resternotomy may minimize the incidence of RV dysfunction.[8] Some of the mechanisms that may be involved include decreased bleeding and fluid shifts, and less disruption of right ventricular geometry with limited incisions.

DISCUSSION

With improvements in LVAD durability and patient survival, surgeons treating patients with heart failure will increasingly be faced with patients requiring LVAD exchange. Although complications remain the primary driver of exchange, the not-so-distant future promises a population of patients who will need routine VAD exchanges after devices run through their "normal" life span. Thus, it is increasingly critical to have an algorithm for performing LVAD exchange that accounts for underlying pathology, patient, and device factors. Planning for exchange begins with the initial LVAD operation with appropriate pump and outflow graft positioning, obsessive maintenance of sterile technique, and protection of the heart and LVAD components with pericardial coverings. Such thoughtful preparation will improve the LVAD exchange experience for all parties.

As the literature suggests lower morbidity with limited incisions, it will be essential to incorporate these techniques into the arsenal of tools for LVAD exchange. Notwithstanding, resternotomy will be necessary in some cases and should be given adequate consideration. No matter the situation, imaging with CT scan (ideally with contrast) will highlight relevant anatomy and contribute to operative planning. We recommend the following framework for choosing between approaches, emphasizing that surgeons should only perform procedures in the setting of adequate personal and institutional expertise (Figure 2):

- For pathology limited to the pump, limited incisions should be prioritized over resternotomy.
- For significant infection involving more than just extrathoracic portions of the driveline, resternotomy should be performed to allow for removal of all hardware

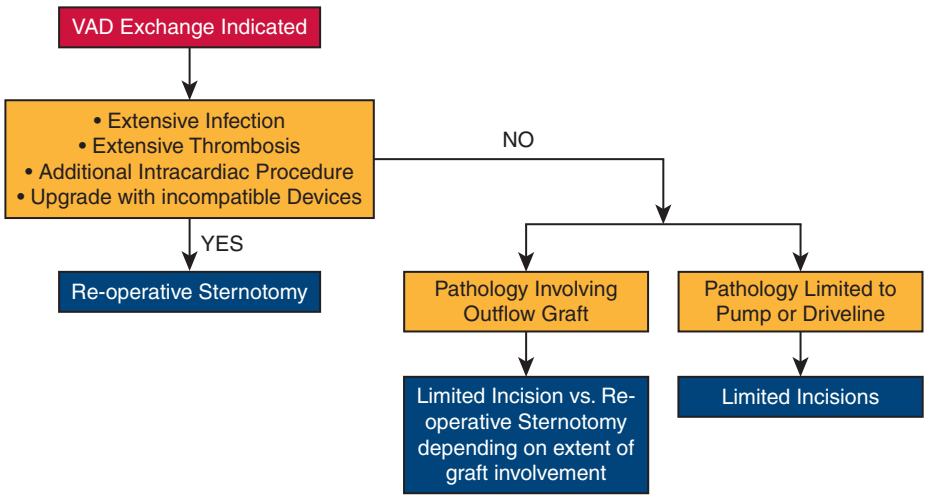

FIGURE 2. Suggested algorithm for choice of surgical approach to VAD exchange. *VAD*, Ventricular assist device.

and adequate irrigation and debridement before reimplantation of a new device. This approach also allows for ring re-siting if necessary.

- For thrombosis involving the outflow graft, resternotomy should be performed, unless pathology is limited to areas that can be completely explanted via limited incisions.
- In patients who have older-generation devices requiring upgrades or have issues with LVAD configuration (graft kinking, suboptimal location of inflow), resternotomy should be performed. Limited incisions may be considered if configuration issues may be remedied without changing all device components.
- Resternotomy will often be required if additional intracardiac procedures are anticipated.

CONCLUSIONS

Flexibility and cautious innovation will necessarily be key components of such an algorithm as improvements in future device generations and in the versatility of surgical techniques will increase the list of considerations and range of options for VAD exchange.

Conflict of Interest Statement

Dr D'Alessandro reports trial support from Transmedics and personal fees from Paragonix, outside the submitted work. Dr Osho reports trial support from Transmedics, also outside the submitted work.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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